REMARKS

Claim Amendments

Claim 1 is amended to recite a composition comprising a detoxified bacterial ADP-ribosylating toxin and a replication-defective gene delivery vehicle. The specification supports this amendment on page 32, lines 25-28: "The present invention also includes pharmaceutical compositions comprising a replication-defective vector . . . in combination with a pharmaceutically acceptable carrier, diluent, or recipient. Further, other ingredients, such as adjuvants, may also be present."

Claims 2-4 are amended to remove the recitation "one or more."

Claims 12-16 and 21-22 are amended to place the claims in a more preferred form.

New claims 35-39 are supported by the specification on page 35, lines 4-10 by teaching that such adjuvants include: "detoxified mutants of a bacterial ADP-ribosylating toxin such as a cholera toxin (CT), a pertussis toxin (PT), or an *E. coli* heat-labile toxin (LT), particularly LT-K63 . . ., LT-R72 . . . , CT-S109 . . ., and PT-K9/G129."

New claim 40 recites an antigen derived from an influenza virus. The specification supports this on page 51, lines 13-14: ". . . immunizations with SIN replicons expressing influenza polypeptide(s) (HA) . . . ."

New claim 41 recites the composition further comprising CpG. The specification supports this on page 51, line 7: ". . . boosted with Ogp140 plus the mucosal adjuvant LTR72 and CpG."

New claim 42 recites wherein the gene delivery vehicle is administered according to a multiple dose schedule. The specification supports this on page 35, line 19: "Dosage treatment may be a single dose schedule or a multiple dose schedule."

Claims 18, 33, and 34 are canceled. No new matter is added.

Rejection of Claims 1-5, 8-21, 29-30, and 33 Under 35 U.S.C. § 112, First Paragraph

Claims 1-5, 8-21, 29-30, and 33 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

The Office Action asserts that "the language introduced in the claims is not completely supported by the language presented at lines 20-30 on page 35." Office Action at page 3, lines 17-18. To advance prosecution, the limitation "which comprises a first course of administration comprising multiple doses followed by a second course of administration" has been removed from the claims. The rejection no longer applies.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 1-5, 8-14, 16-21, 29-30, and 33 Under 35 U.S.C. § 102

Claims 1-5, 8-14, 16-21, 29-30, and 33 stand rejected under 35 U.S.C. § 102 as being anticipated by Malone *et al.* (U.S. Patent No. 6,110,898). Applicants respectfully traverse the rejection.

The Office Action asserts that, "Malone et al. teaches a method of generating an immune response in a subject using the same active method step as described by the claims, by mucosally administering the composition, and using the same active ingredient

as described in the claims, a replication-defective gene delivery vehicle comprising a polynucleotide encoding at least one antigen." Office Action at page 6, lines 9-13.

Amended claim 1 recites mucosal administration of a composition comprising a detoxified bacterial ADP-ribosylating toxin and a replication defective gene delivery vehicle comprising a polynucleotide encoding at least one antigen. Nowhere in Malone is there a teaching of a detoxified bacterial ADP-ribosylating toxin. Thus, amended claim 1 is no longer anticipated by Malone.

Claims 1, 3, 5, 8-12, 18-20, and 31 and claims 1-2, 5, 8, 11-12, 18-20, and 31 stand rejected under 35 U.S.C. § 102 as being anticipated by Belyakov et al. (J. Virol, October 1998, Vol. 72, 10, 8264-8272) and Kano et al. (7th Conf. Retrov. And Opportun. Inf., 2000.S), respectively. Applicants respectfully traverse both rejections.

The Office Action cites both Belyakov and Kano for describing multiple dose schedules. Claim 1 has been amended to remove the multiple dose limitation "which comprises a first course of administration comprising multiple doses followed by a second course of administration" and to recite mucosal administration of a composition comprising a detoxified bacterial ADP-ribosylating toxin and a replication defective gene delivery vehicle. Neither Belyakov nor Kano disclose a detoxified bacterial ADP-ribosylating toxin and thus no longer anticipate amended claim 1.

Applicant respectfully requests withdrawal of the rejection.

Rejection of Claim 15 Under 35 U.S.C. § 103

Claim 15 stands rejected under 35 U.S.C. § 103 as being obvious over Malone *et al.* Applicants traverse the rejection.

The Office Action asserts, "Modifying Malone's gene delivery to include a second construct would have been obvious to one of ordinary skill in the art." Office Action at page 12, lines 13-14.

To make a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Manual of Patent Examining Procedure, 8th ed., § 2142. As discussed above, Malone does not teach or suggest mucosal administration of a composition comprising a detoxified bacterial ADP-ribosylating toxin and a replication defective gene delivery vehicle. Therefore, a *prima facie* case of obviousness has not been made.

Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

BANNER & WITCOFF, LTD.

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By: _____
Dale H. Hoscheit
Registration No. 19,090

Banner & Witcoff, Ltd.
1100 13th Street, N.W.
Suite 1200
Washington, DC 20005-4051
Customer No. 22907